

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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<b>BRAINTREE LABORATORIES, INC.</b>	:	
	:	
<b>Plaintiff,</b>	:	
	:	Civil Action No.: 14-cv-8147-AJN
	:	[rel. 12-cv-6851-AJN]
<b>v.</b>	:	
	:	
<b>TARO PHARMACEUTICALS USA, INC., TARO PHARMACEUTICAL INDUSTRIES, LTD.</b>	:	
	:	
<b>Defendants.</b>	:	

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF BRAINTREE  
LABORATORIES, INC. AND DEFENDANTS TARO PHARMACEUTICAL USA, INC.  
AND TARO PHARMACEUTICAL INDUSTRIES, LTD.'S JOINT MOTION TO STAY**

Plaintiff Braintree Laboratories, Inc. (“Braintree”) and Defendants Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (collectively, “Taro”) hereby jointly move this Court for an administrative stay in this action pending the resolution of the remand proceedings in *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, No. 3:11-cv-01341, pending in the United States District Court for the District of New Jersey. *Braintree v. Novel* is a related case which involves the same patent and same drug at issue in the present case. For the reasons explained below, the parties believe that a stay is appropriate, because resolution of the remand proceedings in *Braintree v. Novel* may be relevant to the just and efficient resolution of this case.

## **I. BACKGROUND**

This is a patent infringement action under the Hatch-Waxman Act. The case concerns U.S. Patent No. 6,946,149 (“the ’149 patent”) and Braintree’s SUPREP® Bowel Prep Kit (“SUPREP”). The ’149 patent is listed in the Food and Drug Administration’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) as covering SUPREP.

Taro has filed Abbreviated New Drug Application (“ANDA”) No. 206431 under 21 U.S.C. § 355(j) seeking to make and sell a generic bioequivalent version of SUPREP. Taro notified Braintree of its ANDA by a letter dated September 2, 2014. On October 9, 2014, Braintree filed the present suit against Taro, alleging, pursuant to 35 U.S.C. § 271(e)(2), that the filing of Taro’s ANDA infringes the ’149 patent.

There are currently three other pending litigations involving the ’149 patent and SUPREP: *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, No. 3:11-cv-01341 (D.N.J.) (“Novel D.N.J.”); *Braintree Laboratories, Inc. v. Breckenridge Pharmaceutical, Inc.*, No. 12-cv-6851-AJN (S.D.N.Y.) (“Breckenridge”); and *Braintree Laboratories, Inc. v. Gator*

*Pharmaceuticals, Inc./KVK-TECH, Inc.*, No. 3:13-cv-398-TJC-MCR (M.D.Fl.) (“Gator”). The status of each of these litigations is explained in turn below.

**A. Braintree v. Novel**

In January 2011, after receiving notice from Novel Laboratories, Inc. (“Novel”) that Novel had filed an ANDA seeking to make and sell a generic copy of SUPREP, Braintree sued Novel for infringement of the ’149 patent in the U.S. District Court for the District of New Jersey. During the original proceedings before that court, United States District Court Judge Peter G. Sheridan construed four disputed claim terms (Novel D.N.J. Dkt. No. 130 at 11), found that Novel’s proposed generic version of SUPREP would infringe the claims of the ’149 patent (Novel D.N.J. Dkt. No. 261 at 18), and ruled that the ’149 patent is valid (Novel D.N.J. Dkt. No. 380 at 46).

Novel appealed two of the claim constructions, and the infringement and validity findings, to the United States Court of Appeals for the Federal Circuit. *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, No. 13-1438 (Fed. Cir.) (“Novel C.A.F.C”). The Federal Circuit affirmed the district court’s validity findings and the district court’s construction of one of the disputed claim terms. (*See* Novel C.A.F.C. Dkt. No. 56 at 3,8). However, the Federal Circuit reversed the district court’s construction of the other disputed claim term and construed another related claim term *sua sponte*. (*See id.* at 9, 11-12). The Federal Circuit vacated the district court’s infringement finding and remanded the case for further factual findings by the district court on infringement. (*See id.* at 12). After denying Novel’s Petition for Rehearing en Banc and Braintree’s Petition for Panel Rehearing and Rehearing En Banc, the Federal Circuit issued its mandate to the district court. (*See* Novel C.A.F.C. Dkt. No. 85).

The remanded *Braintree v. Novel* case is now pending before the District of New Jersey. The matter is scheduled for trial on February 9-11, 2015.

**B. Braintree v. Breckenridge**

In September 2012, after receiving notice from Cypress Pharmaceutical, Inc. (“Cypress”) that Cypress had filed an ANDA seeking to make and sell a generic copy of SUPREP, Braintree sued Cypress for infringement of the ’149 patent in the U.S. District Court for the Southern District of New York. The *Braintree v. Cypress* case was assigned to this Court. It is now pending as *Braintree v. Breckenridge Pharmaceutical, Inc.* (“Breckenridge”), following this Court’s grant of Cypress’ motion to substitute Breckenridge for Cypress.

This Court has placed the *Braintree v. Breckenridge* case on administrative hold in light of the remand proceedings in *Braintree v. Novel*. (See Breckenridge Dkt. No. 65). This Court has ordered the parties to submit a joint status letter on February 13, 2015 if no further action has occurred in the *Braintree v. Novel* case by that date. (See Breckenridge Dkt. No. 71).

The present matter has been assigned to this Court as a related case to the *Braintree v. Breckenridge* case. (See Notice of Case Assignment, 10/24/2014 Docket Entry, Case No.: 14-cv-8147-AJN).

**C. Braintree v. Gator/KVK**

In January 2013, after receiving notice from Gator Pharmaceuticals, Inc. and KVK-TECH, Inc. (collectively, “Gator”) that Gator had filed a New Drug Application seeking approval to market a generic powder version of Braintree’s SUPREP product, Braintree sued Gator for infringement of the ’149 patent in the United States District Court for the Middle District of Florida. After the Federal Circuit issued the mandate in *Braintree v. Novel*, Braintree and Gator filed a joint motion, requesting that the court administratively stay the matter until resolution of the remand in the *Braintree v. Novel* case. (See Gator Dkt. No. 54). United States District Judge Timothy J. Corrigan granted the parties’ motion and ordered that the matter be stayed and administratively closed until further order of the court. (See Gator Dkt. No. 55). The

parties were ordered to file a joint status report regarding the Novel remand on March 9, 2015. (*Id.*).

## II. LEGAL STANDARD

In considering a motion to stay proceedings, the court possesses the “inherent” discretion “to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.” *Louis Vuitton Malletier S.A. v. LY USA, Inc.*, 676 F.3d 83, 96 (2d Cir.2012). When determining whether to exercise its discretion to grant a motion to stay, a court looks to the following factors: “(1) the private interests of the plaintiffs in proceeding expeditiously with the civil litigation as balanced against the prejudice to the plaintiffs if delayed; (2) the private interests of the defendants; (3) the interests of the courts; (4) the interests of persons not parties to the civil litigation; and (5) the public interest.” *Russian Standard Vodka (USA), Inc. v. Allied Domecq Spirits & Wine USA, Inc.*, 523 F.Supp.2d 376, 384 (S.D.N.Y. 2007) (quoting *LaSala v. Needham & Co.*, 399 F.Supp.2d 421, 427 (S.D.N.Y.2005)).

## III. ARGUMENT

The parties believe that an administrative stay in this case is appropriate because all of the factors favor the stay and resolution of the remand in *Braintree v. Novel* may be relevant to the just and efficient resolution of this case. In *Braintree v. Novel*, the Federal Circuit has instructed the district court to make further factual findings regarding whether Novel’s proposed generic version of SUPREP infringes the ’149 patent under the Federal Circuit’s construction of the claims. (*See* Novel C.A.F.C. Dkt. No. 56 at 12). That determination may be relevant to the efficient resolution of the issues in the present case, because the same patent (the ’149 patent) and the same or substantially the same drugs (SUPREP and generic versions of SUPREP) are involved. Because the issues to be resolved in the *Braintree v. Novel* remand may inform how

the present case should be resolved, a stay promotes judicial economy, interests of this Court, the public interest, and the interests of the parties.

#### IV. CONCLUSION

For all of these reasons, Braintree and Taro therefore respectfully and jointly request that this Court treat this case as it has treated the *Braintree v. Breckenridge* case, and as Judge Corrigan has treated the *Braintree v. Gator* case, by placing this case on administrative hold pending the resolution of the remand proceedings in the District of New Jersey in the *Braintree v. Novel* case.

Dated: New York, New York  
January 16, 2015

Respectfully submitted,

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